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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/868,300	DE VEYLDER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-34 and 41-50 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11,12,24-34 and 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-10,13-23 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Applicant's submissions filed on October 7, 2004 has been entered.

Claims 4 and 35-40 are cancelled.

Claims 1 and 5 are currently amended.

Claims 1-3, 5-34 and 41-50 are pending.

Claims 2-3, 11-12, 24-34 and 41-49 are withdrawn from consideration.

Claims 1, 5-10, 13-23 and 50 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

***Claim Rejections - 35 USC § 112***

Claim 1, and claims 5-10, 13-23 and 50 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 1 as amended recites the limitation "the nucleotide sequence encodes a protein having greater than 80% sequence identity to amino acids 96 to 118 of SEQ ID NO:8". This limitation does not find support in the specification as originally filed and thus constitutes new matter.

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Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 5 as amended recites the limitation "an isolated nucleic acid molecule of at least 15 nucleotides in length from a plant halotolerant gene". This limitation does not find support in the specification as originally filed and thus constitutes new matter.

Claims 1, 5-10, 13-23 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed June 2, 2004.

Applicants' arguments filed October 7, 2004 have been fully considered but they are not persuasive.

In response to the Examiner's citation of Ferrando A et al. (Regulation of cation transport in *Saccharomyces cerevisiae* by the salt tolerance gene HAL3. Mol Cell Biol. 1995 Oct;15(10):5470-81) as indicating that amino acids outside of the corresponding region in HAL3 are required for HAL3 salt tolerance, Applicants submit that that an article published after Ferrando et al., i.e., Rodriguez PL et al. (CtCdc55p and CtHa13p: two putative regulatory proteins from *Candida tropicalis* with long acidic domains. Yeast. 1996 Oct;12(13):1321-9, provided herewith as Exhibit 1), contradicts the conclusion by Ferrando et al. Rodriguez et al.

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teach that the acidic C-terminal domain is found in a wide variety of proteins that are not involved in salt tolerance and that are unrelated to the yeast HAL3 protein, and that the acidic domain of the *Candida* HAL3 is likely involved in protein-protein interactions. (reply pages 10-11)

Applicants specifically point to Figure 2 of Rodriguez et al. as showing that the homology between the acidic region of CtHAL3 or ScHAL3 and YKL088w is also low (24.4 and 29.9% sequence identity), whereas the homologies for the second half of the proteins without the acidic region are considerably higher (44.5 and 37.7% sequence identity) (Exhibit 2). Applicants point out that Rodriguez et al. further teach that YKL088w could complement the salt sensitivity of a *hal3::LEU2 S. cerevisiae* strain, and Applicants maintain that since it is well accepted in the art that structural conservation among proteins relates to functional conservation, a person skilled in the art would have reasonably believed at the time the present application was first filed, that the region with the highest sequence similarity would be responsible for the function which is common between these proteins. (reply page 11)

Applicants further point to Espinoza-Ruiz A et al. (*Arabidopsis thaliana* AtHAL3: a flavoprotein related to salt and osmotic tolerance and plant growth. Plant J. 1999 Dec;20(5):529-39, Exhibit 3), who named the isolated plant genes HAL3a and HAL3b and tested whether the plant HAL3a conferred salt tolerance to yeast, which was indeed the case. Applicants point out that Espinosa-Ruiz et al. specifically disclose that while the one striking difference between yeast HAL3 and *Arabidopsis* AtHAL3 is the presence in the fungal protein of a long acidic tail which had been reported by Ferrando et al. to be essential to improve NaCl tolerance, complementation by Espinoza-Ruiz A et al. of a yeast HAL3 null mutant using both a truncated yeast HAL3

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devoid of the acidic tail and a chimeric AtHAL3 to which the yeast acidic tail was fused showed that complementation of the HAL3 mutation depended little on the presence of an acidic tail.

Applicants thus maintain that the rejection of claims predicated on the region conferring salt tolerance residing in the C-terminal domain is inaccurate based on the teachings by Rodriguez et al. and Espinosa- Ruiz et al. and should be reconsidered by the Examiner. (reply pages 11-12).

The Examiner acknowledges Applicant's response to the prior citation Ferrando et al. (1995), and acknowledges in particular the teachings of Espinoza-Ruiz A et al. (Exhibit 3) that a truncated HAL3 coding sequence lacking the C-terminal domain of yeast retains the ability to confer salt tolerance to yeast, indicating that the ability of HAL3 to confer salt tolerance resides at least in part in a region located outside the C-terminus. The rejection is maintained, however, as the rejection was not predicated solely on the teachings of Ferrando et al.

The rejection is maintained because neither the specification nor the prior art indicates whether the conserved structural feature of the disclosed sequence, namely amino acids 96-118 of SEQ ID NO:8, is correlated with any specific function, or with a function required to practice Applicants' claimed invention. Further, claim 1 as currently amended is not limited to a conserved structural feature of the disclosed sequence. The language of currently amended claim 1 also allows for proteins having greater than 80% sequence identity to amino acids 96 to 118 of SEQ ID NO:8. Neither the specification nor the prior art describe even one such sequence. The specification describes a 201 amino acid sequence of SEQ ID NO:8 obtained from the plant *Arabidopsis thaliana*. The prior art describes a 562 amino acid HAL3 sequence obtained from *Saccharomyces cerevisiae*. As Applicant has noted, the 562 amino acid HAL3 sequence differs

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from SEQ ID NO:8 in 5 amino acids in the region spanning residues 96-118 of SEQ ID NO:8. Accordingly the HAL3 protein has slightly less than 80% sequence identity (78%) to amino acids 96 to 118 of SEQ ID NO:8. Additionally, the HAL3 sequence differs from SEQ ID NO:8 at 5 specific locations (corresponding to amino acids 107, 108, 109, 110 and 114 of SEQ ID NO:8), by having 5 specific amino acid substitutions (i for V, l for M, v for I, v for I, t for S, respectively) at these specific locations in the region spanning residues 96-118 of SEQ ID NO:8 (alignment, Applicants' Exhibit B). Accordingly the variation between the HAL3 protein and SEQ IDNO:8 with respect to amino acids 96 to 118 of SEQ ID NO:8 is specific with respect to both the position and the identity of the amino acids that account for the variation.

Claims 1, 5-10, 13-23 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed June 2, 2004.

Applicants' arguments filed October 7, 2004 have been fully considered but they are not persuasive.

Applicants point to Example 4 of the specification as clearly stating that the HAL3 gene is useful for conferring salt tolerance on plants and to improve plant growth under conditions of salt stress, and to the description on p34, lines 5-8, stating that "... overproduction of the cell cycle interacting protein of the invention enhances growth and results in cell division to be less sensitive to an arrest caused by environmental stress such as salt, ...". Applicants point out that

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similar statements are also made on page 42, lines 2-4, page 49, lines 8-11, page 61, line 7 6-19, page 62, lines 5-8 and line 29 to page 63, line 5. (reply page 13)

Applicants' assertions in the specification that the claimed HAL3 gene has specific functions do not enable the rejected claims given the unpredictability of amino acid sequence variants being functionally equivalent.

Applicants also point to Ferrando A et al. (Regulation of cation transport in *Saccharomyces cerevisiae* by the salt tolerance gene HAL3. *Mol Cell Biol.* 1995 Oct;15(10):5470-81), who demonstrated that the related yeast gene is involved in yeast salt tolerance, and later studies by Espinoza-Ruiz et al. (Exhibit 3) and by Yonamine I et al. (Overexpression of NtHAL3 genes confers increased levels of proline biosynthesis and the enhancement of salt tolerance in cultured tobacco cells. *J Exp Bot.* 2004 Feb;55(396):387-95, provided herewith as Exhibit 4), who showed that the plant homologues of yeast HAL3 perform the same function in plants. Applicants maintain that the fact that some of the references submitted as Exhibits 1 through 4 were published after the original filing date of the present application is appropriate since the teachings of the published references do not add to the teachings of the present specification and demonstrate results using techniques available at the relevant time. See *Gould v. Quigg*, 822 F.2d 1074, 3 USPQ 2d 1302 (Fed. Cir. 1987). (reply pages 13-14)

Applicants' cited post-filing date art does not enable the claimed invention because the cited references did not utilize the nucleotide sequences recited in the rejected claims (a DNA



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molecule encoding SEQ ID NO:8 or encoding a protein having greater than 80% sequence identity to amino acids 96 to 118 of SEQ ID NO:8).

Applicants point out that the Examiner has posited on page 7 that the record indicates that the region spanning residues 96-118 of SEQ ID NO: 8, corresponding to amino acids 376-398 in HAL3 is highly conserved, and that the HAL3 sequence differs from SEQ ID NO: 8 in 5 amino acids in this region. In this respect, Applicants point out that the Examiner alleges that the record does not indicate in what way this region is correlated to HAL3 function or what other types of amino acid substitutions would be functionally tolerated at these specific locations. As discussed above, Applicants maintain that the claims have been amended and remarks provided as to why a person skilled in the art would consider preferentially the C-terminal half without the acidic region of yeast HAL3 as the part conferring salt tolerance. A person skilled in the art would also appreciate that within this C-terminal half, the conserved residues are the first candidates for being responsible for conferring salt tolerance. (reply page 14)

That a person skilled in the art would consider preferentially the C-terminal half without the acidic region of yeast HAL3 as the part conferring salt tolerance, and that a person skilled in the art would also appreciate that within this C-terminal half the conserved residues are the first candidates for being responsible for conferring salt tolerance does not establish which conserved residues in this region of the protein are responsible for conferring salt tolerance, because the fact that an amino acid residue is conserved is not always functionally significant. See, for example, Falcon-Perez JM et al. (Functional domain analysis of the yeast ABC transporter Ycf1p by site-directed mutagenesis. J Biol Chem. 1999 Aug 13;274(33):23584-90), who generated twenty-two

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single amino acid substitutions or deletions by site-directed mutagenesis in the nucleotide binding domains, the proposed regulatory domain, and the fourth cytoplasmic loop of the yeast cadmium factor (Ycflp) vacuolar protein. Two conserved amino acid residues, Glu(709) and Asp(821), were found to be unnecessary for Ycflp biogenesis and function.

Applicants maintain that the present application clearly teaches a method of obtaining the presently claimed nucleic acid molecules, host cells, vectors, transgenic plants comprising the foregoing, as well as methods for producing a cell cycle interacting protein, and that a person skilled in the art would know how to subject plants to salt stress and how to evaluate the effects of salt on plant growth. Applicants maintain that these types of experiments are routine and commonly known in the art, and that although it might have taken a considerable amount of experimentation at the time of filing the present application to identify derivatives and homologs to Applicants' halotolerant protein comprising the amino acid sequence set forth in SEQ ID NO:8, such experimentation would not have been considered undue. (reply pages 14-16)

Applicants' disclosure of techniques that are commonly known in the art does not enable the claimed invention. Given the unpredictability of amino acid sequence variants being functionally equivalent, it would require undue experimentation for one skilled in the art to practice the claimed invention. In this regard the undue experimentation does not lie in the practice of techniques that are known to and within the abilities of one skilled in the art. The undue experimentation lies in the selection of coding sequences that would likely produce a protein having the desired function. Applicants have not provided sufficient guidance with respect to which of the sequences recited in the claims (a DNA molecule encoding SEQ ID NO:8

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or encoding a protein having greater than 80% sequence identity to amino acids 96 to 118 of SEQ ID NO:8) would likely produce a protein having the desired function (enhancement of cell division and/or growth and/or enhancement of stress tolerance) and which would not, as Applicant has not disclosed even a single sequence encompasses by the rejected claims that has this effect.

Applicants point to page 8 of the previous Office Action where the Examiner alleges that the claimed invention is not enabled because the polypeptide that exhibits homology to HAL3 lacks the HAL3 region required for salt tolerance activity as could be derived from Ferrando et al. However, as discussed above, Applicants maintain that the later publications by Rodriguez et al. and Espinosa-Ruiz et al. demonstrate that the assumption of Ferrando et al. was indeed wrong. (reply page 17).

The teachings of Rodriguez et al. and Espinosa-Ruiz et al. with respect to the assumption of Ferrando et al. are acknowledged as set forth above. The rejection is maintained, however, as the rejection was not predicated solely on the teachings of Ferrando et al.

Applicants point to page 8 of the previous Office Action where the Examiner alleges that the claimed invention is not enabled because the effect of making amino acid substitutions in a conserved region of a polypeptide is unpredictable, thereby citing Rhoads DM et al. (Regulation of the cyanide-resistant alternative oxidase of plant mitochondria. Identification of the cysteine residue involved in alpha-keto acid stimulation and intersubunit disulfide bond formation.

J Biol Chem. 1998 Nov 13;273(46):30750-6). Applicants point out, however, that the paper by

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Rhoads et al. does not teach anything about HAL3, and that the substitution made by Rhoads et al. from Cys (a hydrophilic and polar amino acid) to Ala (a hydrophobic non-polar residue) is not a conserved substitution and thus likely to be unpredictable. Applicants maintain that one skilled in the art would know to make conserved substitutions in areas showing great homology to other halotolerant proteins, such as in amino acids 96 to 118 of SEQ ID NO:8. (reply page 17)

The Examiner maintains that the teachings of Rhodes et al. are relevant to the unpredictability of the functional effect of making amino acid substitutions in a conserved region of any polypeptide, including HAL3 or its homologues. The Examiner also maintains that rejected claims are not limited to proteins having conservative amino acid substitutions in a conserved domain. The Examiner further maintains that limiting the rejected claims to proteins having conservative amino acid substitutions in the conserved domain would not overcome the rejection because the functional effect of making conserved amino acid substitutions in a conserved region of a polypeptide is unpredictable. See, for example, Defeo-Jones D et al. (Substitution of lysine for arginine at position 42 of human transforming growth factor-alpha eliminates biological activity without changing internal disulfide bonds. Mol Cell Biol. 1989 Sep;9(9):4083-6), who prepared site-specific substitution mutants of transforming growth factor-alpha (TGF-alpha) in order to identify critical residues that govern TGF-alpha-EGF receptor binding. Semiconservative substitutions at positions 4, 12, 18, and 45 decreased TGF-alpha biological activity 2.1- to 14-fold, but the conservative substitution of lysine for arginine at position 42 completely eliminated TGF-alpha biological activity (abstract; page 4084 Table 1).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite in the recitation of “plant halotolerant gene”. It is unclear in what way the gene is associated with plants and halotolerance. Does the gene make plants halotolerant when expressed? Is the gene obtained from halotolerant plants? In this regard the Examiner notes that the specification does not define “plant halotolerant gene”.

Claims 1, 5-10, 13-23 and 50 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record set forth in the office action mailed June 2, 2004, and for the reasons set forth below.

Claims 1, 5-10, 13-23 and 50 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed June 2, 2004, and for the reasons set forth below.

Applicants' arguments filed October 7, 2004 have been fully considered but they are not persuasive.

Applicants point out that the specification is replete with teachings of the presently claimed invention being useful for conferring salt tolerance in plants, e.g., page 34, lines 7-10,

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page 49, lines 9-11, page 61, lines 9-20, page 62, lines 5-8 and line 29 to page 63, line 5.

Applicants maintain that apparently the Examiner believes that the assertion in the specification for a specific and substantial utility would not be considered credible by a person of ordinary skill in the art. Applicants also point to the USPTO's Utility Guidelines, Fed. Reg. 66(4):1092-1099 (Friday, January 5, 2001) which provide "credibility is assessed from the perspective of one or ordinary skill in the art in view of the disclosures and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement."

(reply page 18)

The Examiner maintains that the outstanding rejection was not predicated on the credibility of the assertions set forth in the specification. The outstanding rejection was based on the failure of the specification to demonstrate the existence of even a single specific and substantial utility or well established utility for a polypeptide of SEQ ID NO:8.

With respect to the Examiner's comments that neither Applicants nor the prior art provide any evidence that the conserved structural feature corresponding to the functional HAL3 sequence, recited as amino acids 96 to 118 in currently amended claim 1, is sufficient to impart salt tolerance activity on SEQ ID NO:8, Applicants submit the following remarks.

As previously discussed in the submission under 37 C.F.R. 1.114, filed as part of the RCE in the above-identified application on March 5, 2004, Applicant's V889 halotolerant protein (SEQ ID NO:8) and HAL3 from *Saccharomyces cerevisiae* share a mere 13% amino acid

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sequence identity and a 21.7% amino acid sequence similarity. See Exhibit B of March 5, 2004 submission. The most conserved region between the two proteins correlates to amino acids 96 to 118 of SEQ ID NO:8, the area of identity being less than the 80% identity as presently claimed. Yet Applicants accurately described the utility of the presently claimed invention, as later publications have confirmed. Specifically, as the publications provided herewith as Exhibits 1-4 clearly illustrate, although the sequence of S1S2 and YK1088 are only 23.6% identical, YKL088 is able to complement a salt sensitive yeast strain in the same way as S1S2. Similarly, although the sequence identities of AtHAL3a and AtHAL3b with S1S2 are lower compared to YKL088 with SIS2, the sequence conservation is in the same region of the proteins. Thus, the findings of those of skill in the art, provided herewith as Exhibits 1-4, offer objective evidence supporting the utility of the present invention. See *Gould v. Quigg*, 822 F.2d 1079, 3 USPQ 2d 1302 (Fed. Cir. 1987)(later dated publication may be used as evidence of the level of ordinary skill in the art at the time of the application and as evidence that disclosed device would have been operative). Applicants have therefore established a probative relation between the submitted evidence of Exhibits 1-4 and the originally disclosed properties of the claimed invention.

Applicants' arguments do not overcome the rejection because the later publications have not confirmed Applicants' description of the utility of the presently claimed invention, since the later publications cited by Applicants did not utilize the nucleotide sequences recited in the rejected claims (a DNA molecule encoding SEQ ID NO:8 or encoding a protein having greater than 80% sequence identity to amino acids 96 to 118 of SEQ ID NO:8).

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***Claim Rejections - 35 USC § 102***

Claim 5 remains rejected under 35 U.S.C. 102(b) as being anticipated by Ferrando et al. (Molecular and Cellular Biology, October 1995, Vol. 15, No.10, pages 5470-5481, Applicants' Exhibit A), for the reasons of record set forth in the office action mailed June 2, 2004, and for the reasons set forth below.

Applicants' arguments filed October 7, 2004 have been fully considered but they are not persuasive.

Applicants argue that since claim 5 as amended requires a nucleic acid molecule isolated from a plant halotolerant gene Ferrando et al. no longer anticipates the rejected claim (reply pages 19-20).

The Examiner maintains that the source of the claimed nucleic acid molecule (plant) does not distinguish the claimed nucleic acid molecule from the nucleic acid molecule taught by Ferrando et al. (which was obtained from yeast), because plant and yeast nucleic acid molecules are composed of the same material (nucleotides) and utilize the same genetic code. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Examiner  
Art Unit 1638

CC

A handwritten signature in black ink, appearing to read "Amy Nelson", with a long horizontal flourish extending to the right.

AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600